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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SALVOZA, M FRANCO G	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,176	MUNDT ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *11-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 have been amended.

Election/Restrictions

Applicant's election with traverse of Group I and species of "serine" at positions 222 and 220 and SEQ ID NO: 1 in the reply filed on September 14, 2006 is acknowledged. The traversal is on the ground(s) that all the species meet the definition of the claimed mutant and are different embodiments of the same invention; examining all the species is not unduly burdensome.

This is not found persuasive because as indicated in the Restriction, the separate species and sequences recite independent and distinct inventions as further indicated by separate status in the art, and separate searches would be required for each, therefore constituting an undue search burden. The requirement is still deemed proper and is therefore made FINAL.

Claims 11-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 14, 2006.

Claims 1-10 are under consideration.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code in section [0104]. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: it does not contain a description of the drawings.

Appropriate correction is required. Applicant is reminded of the content of the specification.

Content of Specification

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the classic IBDV mutant according to claim 1, wherein the mutant comprises one or more mutations in a classic VP2 coding region, such that the coding region comprises, (i) a codon for the amino acid at position 222 encoding an amino acid selected from serine, and (ii) a nucleotide sequence encoding an amino acid sequence selected from the group consisting of SEQ ID. No. 1.

Claim 4 recites a classic IBDV mutant according to claim 3, wherein the coding region comprises a codon for the amino acid at position 330 encoding an amino acid selected from serine.

It is not clear to what amino acid position 222 or 330 in either of these claims

corresponds, or the basis of determining where amino acid position 1 begins. While claim 1 indicates classic IBDV mutant, claim 1 also recites a mutant, which encompasses deletions and insertions which would change the numbering of the residues.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an IBDV mutant comprising a mutation at position 222 as well as nucleotide sequence SEQ ID NO.1 at positions 318-323, does not reasonably provide enablement for the broad scope of "one or more mutations" that would enable the IBDV mutant to also successfully bind to moab B69 as well as moab 67. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claim 1 recites a classic infectious bursal disease virus (IBDV) mutant that expresses a VP2 protein that binds with monoclonal antibody (moab) B69, wherein the VP2 protein, also binds with moab 67, secreted by hybridoma cell lines HB-9437 and HB-11122, deposited at the ATCC, Rockville, USA, respectively.

Claims 2, 3, 4, 5, 6 recite the classic IBDV mutant according to claim 1, wherein the VP2 protein binds with moab B69, moab 67 and moab R63, secreted by hybridoma cell line HB-9490, deposited at the ATCC, Rockville, USA; wherein the mutant comprises one or more mutations in a classic VP2 coding region, such that the coding region comprises, (i) a codon for

the amino acid at position 222 encoding an amino acid selected from serine, and (ii) a nucleotide sequence encoding an amino acid sequence selected from the group consisting of SEQ ID. No. 1 at positions 318-323; wherein the mutant comprises one or more mutations in a VP2 coding region of IBDV strain D78; wherein the mutant comprises a genomic segment A of a classic IBDV, preferably of IBDV strain D78; wherein the coding region comprises a codon for the amino acid at position 330 encoding an amino acid selected from the group consisting of arginine or and serine.

Claims 7-10 recite a vaccine comprising the classic IBDV mutant and other components.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 P 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988) and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

In this case, the amount of direction or guidance presented, the presence or absence of working examples, the state of the prior art and the breadth of the claims are most relevant.

As indicated above, claims 1-10 broadly recite and reads on any IBDV mutant that expresses any VP2 protein that binds with B69 and 67; that further binds with R63; wherein the mutant comprises ***one or more mutations*** (emphasis added) including a substitution at position

222; the nucleotide sequence SEQ ID NO.1-5.

The specification provides Table 2 (and the binding results in Table 4) teaching at a minimum specific amino acid substitutions at positions 222, 318-323, 330 as well as the corresponding sequences that enable a skilled person to generate classic IBDV mutants that express a VP2 protein that comprises B69 and 67 epitopes.

However, the specification does not provide support for the full scope of point mutations that can be made to other portions of the VP2 protein in any classic IBDV to mutate the virus and enable binding to moabs B69 and 67, and consequently R63.

VP2, as taught in applicant's specification and known in the art, consists of 512 amino acids, with portions or variability and hypervariability located therein. References reviewing the state of the art for these particular diseases indicate crucial sequences for substitutions between residues 212-332, esp. 212-223 and 314-324 ("Molecular basis of antigenic variation in infectious bursal disease virus"; Vakharia et al. (1994)), which comprise in total 20 amino acids and possible substitutions. The consequence of other additional point mutations (as indicated by claims 3, 5 reciting "one or more mutations" as well as claims 1, 2 broadly indicating binding to the designated moabs) on binding to the claimed antibodies is not clear, as additional point mutations affect folding and conformational epitopes to have varying consequences on antigenicity and binding among antibodies for with wide variety of classic IBDV strains.

In view of these factors, the application has not provided sufficient information to enable those in the art to practice the claimed invention without undue experimentation.

Claims 1-10 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

While the specification provides a method for readily identifying the cited hybridomas, one does not appear to be readily available material as the hybridoma HB-11122 could not be found through a search of the ATCC resources. Additionally, the deposit requirements have not been met for all three claimed hybridomas (HB-9437, HB-11122, HB-9490).

The cited hybridoma cell line HB-11122 is required to practice the claimed invention as recited in claim 1. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit. See 37 CFR 1.802.

One cannot practice the claimed invention without access to the antibodies produced by the hybridoma cell line HB-11122. Therefore, access is required to practice the invention.

Deposit of hybridoma cell line HB-11122 in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112, because the cell lines would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions

imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.
In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claims 7-10 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 recites a vaccine for use in the protection of poultry against disease caused by IBDV infection.

See the recitation to the Wands factors above.

In this case, the quantity of experimentation necessary; the amount of direction or guidance presented; the absence of working examples; the state of the prior art; the breadth of the claims are most relevant.

As indicated above, claim 7 recites a vaccine for use in the protection of poultry against disease caused by IBDV infection. Thus the claims - by reciting "protection of poultry against disease caused by IBDV infection" - read upon vaccines of IBDV and the full scope of vaccines and protection.

References reviewing the state of the art for these particular diseases indicate limited experimental results for vaccine for IBDV, such as an immune complex vaccine for which the mechanism is not yet clear; DNA vaccines; and VP2 proteins that elicit immunogenic responses (p. 159; Muller et al, "Research on infectious bursal disease-the past, the present and the future," Veterinary Microbiology, 2003). However, the instant invention recites a vaccine comprising IBDV with mutated VP2.

Applicant's disclosure contains only very limited data, only teaching eliciting an immune response through administration of the composition in Example 4, page 28. The disclosure does not sufficiently teach beyond this limited data to counter the teachings in the art and enable the full scope of the claim towards protection against disease caused by IBDV infection.

In view of these factors, the application has not provided sufficient information to enable those in the art to practice the claimed invention without undue experimentation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Vakharia et al., "Molecular basis of antigenic variation in infectious bursal disease virus" 1: *Virus Res.* 1994 Feb; 31(2): 265-73 is further noted for teaching positions for binding to Mab67.

2. Jackwood et al., "Molecular identification of infectious bursal disease virus strains," *Avian Dis.* 1997 Jan-Mar; 41(1):97-104 is cited for teaching the presence of serine at amino acid position 222 in IBDV variants.

3.: Dormitorio et al., "Sequence comparisons of the variable VP2 region of eight infectious bursal disease virus isolates," *Avian Dis.* 1997 Jan-Mar;41(1):36-44 is cited for teaching the presence of threonine at amino acid position 222 in certain IBDV variants.

4. Jackwood et al., "Identification and comparison of point mutations associated in classic and variant infectious bursal disease viruses," *Virus Res.* 1997 Jun;49(2):131-7 is cited for teaching amino acid variations at position 222 in IBDV variants.

5. Whetzel et al., "Comparison of neutralizing epitopes among infectious bursal disease viruses using radioimmunoprecipitation," 1: *Avian Dis.* 1995 Jul-Sep;39(3):499-506 is cited for teaching MabR63 and B69 binding for IBDV strain D78.

6. Eterradossi et al., "Critical amino acid changes in VP2 variable domain are associated with typical and atypical antigenicity in very virulent infectious bursal disease viruses," *Arch Virol* 143, pp. 1627-16346 (1998) for teaching changes in proline at amino acid position 222.

7. Yu et al., "Molecular characteristics of full-length genomic segment A of three

infectious bursal disease viruses in China: two attenuated strains and one virulent field strain" *Avian Dis.* 2001 Oct-Dec;45(4):862-74 is cited for teaching genomic segment A as well as substitutions at amino acids including position 330.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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